

Appl. No. 10/807,974  
Dated: October 7, 2008  
Reply to Office action of July 8, 2008

### **AMENDMENTS TO THE DRAWINGS**

Please amend the drawings, replacing currently-pending drawing sheets with corresponding *Replacement Sheets* submitted as an Appendix hereto. Drawing sheets listed below have had amendments made as further described in the Specification. Replacement Sheets not listed below represent the corresponding sheets as-filed such that a complete set of drawing sheets is included herewith. No new matter has been added with these amendments.

- *Replacement Sheet 1* including Figure 1;
- *Replacement Sheet 2* including Figure 2;
- *Replacement Sheet 6* including Figures 7, 8;
- *Replacement Sheet 8* including Figure 11;
- *Replacement Sheet 10* including Figures 14, 15;
- *Replacement Sheet 11* including Figure 16;
- *Replacement Sheet 15* including Figures 23-26;
- *Replacement Sheet 16* including Figure 27;
- *Replacement Sheet 17* including Figures 28, 29;
- *Replacement Sheet 20* including Figures 32, 33;
- *Replacement Sheet 23* including Figure 37;
- *Replacement Sheet 24* including Figures 38, 39, 40;
- *Replacement Sheet 25* including Figures 41A, 41B; and
- *Replacement Sheet 26* including Figure 42.

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### **REMARKS**

Claims 1-9, 20-26, 34-38, and 53-72 were before the Examiner for consideration, Claims 10-19, 27-33, and 39-52 having been previously withdrawn. In this paper, Claims 1, 23-26, and 36-37 have been amended, no claims have been canceled, and no claims have been added. Accordingly, Claims 1-9, 20-26, 34-38, and 53-72 remain before the Examiner for consideration. No new matter has been added with these amendments.

#### **Request for Reconsideration of the Examiner's Withdrawal of Claims 53-72**

In the Office Action, it was indicated that Claims 53-72 were withdrawn as being drawn to a non-elected species. For at least the reasons discussed below, Applicant respectfully submits that Claims 53-72 correspond to the elected species. Therefore, Applicant requests reconsideration of the withdrawal of Claims 53-72 and examination of these claims in a new non-final Office Action.

Specifically, in the Office Action, it was noted that a device having a seal at the distal end of the tubular member where the seal is sized and configured to form a seal with an instrument when instrument is in place within the working channel of the tubular member and to form a zero seal when no instrument is in place within the working channel of the tubular member is not shown in the elected species (Species A, Figure 6-10). The Office Action further noted that "it is not disclosed or shown that the seal of

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the elected species is sized and configured to form a seal with an instrument when an instrument is in place within the working channel of the tubular member."

However, Applicant notes that the features identified in the Office Action are both shown and described with respect to the elected species in the Application as-filed. For example, at least Figures 7 and 8, and descriptive text thereof at the paragraph beginning on page 13, line 17 of the specification as-filed (paragraph [0065] of the published patent application) relate to an access device having a seal system that allows a body cavity to be sealed when laparoscopic surgical instruments are inserted through a channel of the access device. Moreover, Figures 9 and 10, and descriptive text thereof at the paragraph beginning on page 14, line 3 of the specification as-filed (paragraph [0066] of the published patent application) describe and illustrate a seal comprising a septum "having an orifice 145 that is sized and configured to seal in conjunction with a specific range of usable instruments." (Specification, page 14, line 7-8).

Thus, for at least the reasons discussed above, Applicant respectfully submits that the subject matter of Claims 53-72 is described and shown in the Application as-filed with respect to the elected species. Accordingly, Applicant respectfully requests reconsideration of the withdrawal of Claims 53-72 and the consideration of these claims in a new non-final Office Action.

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### **Regarding the Objections to the Drawings**

In the Office Action, the drawings were objected to for failing to include reference signs 130a, 130b, 132, and 440, which are mentioned in the description. In the above section entitled Amendments to the Drawings, Applicant has requested the entry of replacement sheets in which Figure 27 has been amended to include element 440, Figure 32 has been amended to include elements 130a, 130b, and 132, and Figure 33 has been amended to include elements 130a and 130b. No new matter has been added with this amendment.

In the Office Action, the drawings were objected to for including reference characters 2, 12, 30, 210, 220, 252, 255, 109, 142, 362, 365, 376, 400, 461, 480, 415, 412, 118, 119, 391, 391b, 134, 135, 602, 622, 670, 650, 680, 630, 710, and 712, which are not mentioned in the specification. In the above section entitled Amendments to the Drawings, Applicant has requested the entry of replacement sheets in which Figures 1, 2, 7, 8, 11, 14, 15, 16, 23, 24, 25, 27, 28, 32, 37, 40, 41A, 41B, and 42 have been amended. In these amendments, reference characters 2, 12, 30, 210, 220, 252, 255, 109, 376, 400, 415, 412, 441, 460, 461, 480, 118, 119, 134, 135, 602, 622, 630, 650, 670, 680, 710, and 712 have been deleted. On Figure 14, reference characters 141 and 142 have been amended to read 140 and 145 respectively. In the above section entitled Amendments to the Specification, the Specification has been amended to include reference to reference characters 362, 365, 391, and 391b. The Specification has also been amended above to remove reference to reference characters 441 and

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460 (which have been deleted from the corresponding figure). No new matter has been added with this amendment.

Accordingly, the objections to the drawings are no longer applicable to the present Application. Thus, the Applicant respectfully requests that the Examiner withdraw these objections.

#### **Regarding the Objections to the Specification**

In the Office Action, the disclosure was objected to on the basis of certain informalities. An apparent grammatical error was noted on line 20 of page 13. In the above section entitled Amendments to the Specification, Applicant has directed entry of an amendment to include reference to the "access device 100." In the Office Action, inconsistent usage of reference characters 120 and 140 was noted. In the above section entitled Amendments to the Specification, Applicant has directed entry of an amendment clarifying the usage of these reference characters. No new matter has been added with these amendments.

Accordingly, the objections to the specification are no longer applicable to the present Application. Thus, the Applicant respectfully requests that the Examiner withdraw these objections.

#### **Regarding the Objections to the Claims**

In the Office Action, Claims 23, 25, 26, 37, and 38 were objected to on the basis

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of certain informalities. For at least the reasons discussed below, Applicant respectfully submits that these objections are no longer applicable to the pending claims.

Regarding Claim 23, the Office Action indicates that it is unclear if the proximal end refers to the proximal end of the elongate tubular member or the proximal end of the along the shaft. Claim 23 has been amended to clarify the recitations therein. Regarding Claims 25 and 26, the Office Action indicated a similar lack of clarity regarding the terms thereof. Upon review, Applicant noted similar terminology in Claim 24. Claims 24, 25, and 26 have likewise been amended to clarify the recitations therein.

Regarding Claim 37, the Office Action indicated that there was insufficient antecedent basis for the limitations "the occlusive lip portions" and "the seal." Claim 37 has been amended to provide antecedent basis and clarify these terms. The Office Action did not specify reasons for the objection of Claim 38. Accordingly, Applicant assumes Claim 38 was objected to as dependent from Claim 37. Thus, the amendments to Claim 37 should likewise address the objections to Claim 38.

For at least the reasons discussed above, the objections to Claims 23, 25, 26, 37, and 38 are no longer applicable. Thus, Applicant respectfully requests that the Examiner withdraw these claim objections.

#### **Regarding the Rejections under 35 U.S.C. § 112**

In the Office Action, Claims 1-9, 20-26, and 34-38 were rejected under 35 USC

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§112 as failing to comply with the enablement requirement. More specifically, the Office Action indicated that it was unclear how the zero seal can flow with the septum seal relative to the tubular member. In this paper, Claim 1 has been amended to remove the recitation of the floating aspect of the seals relative to the tubular member. Accordingly, Applicant respectfully submits that this rejection is no longer applicable to Claim 1. In the Office Action, no specific basis for lack of enablement was presented with respect to Claims 2-9, 20-26, and 34-38, which depend from Claim 1. Accordingly, Applicant assumes that these claims were rejected for depending from a rejected base claim. Thus, since this rejection is no longer applicable to Claim 1, the rejection is likewise no longer applicable with respect to Claims 2-9, 20-26, and 34-38.

Claim 36 was rejected under 35 U.S.C. § 112 as being indefinite. More specifically, the Office Action indicated that the phrase "or the like" renders the claim indefinite. In this paper, Applicant has amended Claim 36 to further define the claimed subject matter.

Accordingly, for at least the reasons discussed above, Applicant respectfully submits that all of the rejections under 35 U.S.C. § 112 are no longer applicable to the pending claims. Accordingly, Applicant respectfully requests that these rejections be withdrawn.

#### **Regarding the Rejections in View of Lafontaine**

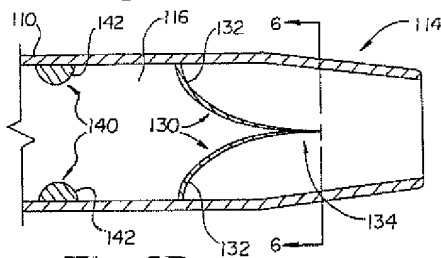
In the Office Action, Claims 1-9, 20-24, and 34-38 were rejected under 35

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U.S.C. § 102(b) as being anticipated by Lafontaine (U.S. Patent No. 6,520,939). Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Green et al. (U.S. Patent No. 6,497,716). For at least the reasons discussed below, Applicant respectfully traverses these rejections.

Lafontaine relates to a hemostasis valve for use with vascular introducer sheaths, catheters, Y-adapters, and the like. (Lafontaine, col. 1, lines 6-9). As illustrated in Figure 5A, reproduced below, Lafontaine describes an introducer sheath including an active hemostasis valve 130 and a passive hemostasis valve 140. (Lafontaine, col. 4, lines 6-7). The active hemostasis valve 130 comprises a plurality of leaflets or flaps 132. (Lafontaine, col. 4, lines 30-31). The passive hemostasis valve 140 is normally open to allow devices to freely pass therethrough, and comprises a flexible polymeric O-ring. (Lafontaine, col. 4, lines 47-64).

**Fig. 5A**



Claim 1 relates to a surgical access device comprising, among other limitations, an elongate tubular member, a septum seal integrally formed at the distal end of the tubular member, and a zero seal disposed at the distal end of the tubular member and distal to the septum seal. Lafontaine fails to disclose all of the elements of the recited



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surgical access device. For example, Lafontaine fails to disclose a septum seal. Rather, as noted above, Lafontaine discloses a passive hemostasis valve comprising an O-ring. Indeed, Lafontaine describes that with the use of certain tools, the O-ring provides a *gap-fit*, allowing the active hemostasis valve to seal against a device inserted therethrough. (Lafontaine, col. 4, lines 58-64, Figure 5B). In connection with the background to the Lafontaine device, Lafontaine does describe a "gasket" having a hole or slit therethrough. (See, e.g., Lafontaine, col. 1, lines 27- 41, Figures 2A, 2B). However, Lafontaine describes these gasket configurations only in relation to admitted prior art vascular access systems that, unlike the access device recited in Claim 1, do not include another seal. Furthermore, Lafontaine emphasizes perceived undesirable performance characteristics of each of these gasket configurations to assert the desirability of the O-ring. (Lafontaine, col. 1, lines 42-55). Thus, Lafontaine teaches away from using one of the described gaskets as either an active hemostasis valve or a passive hemostasis valve in the described surgical access device.

Accordingly, for at least the reasons discussed above, Claim 1 is distinguishable over the applied art. Claims 2-9, 20-24, and 34-38 depend from Claim 1 and recite additional novel and nonobvious limitations thereon. Therefore, Claims 2-9, 20-24, and 34-38 are distinguishable over the applied art for at least the reasons discussed above with respect Claim 1.

As noted above, Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Green et al. Claims 25 and 26 depend

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from Claim 1 and recite additional novel and nonobvious limitations thereon. As discussed above, Lafontaine fails to disclose or suggest all of the limitations of Claim 1. Green likewise fails to disclose or suggest the deficiencies of Lafontaine with respect to Claim 1. Green relates to a safety trocar with a sharp cutting tip that retracts into the cannula to minimize the likelihood of inadvertent injury to tissue. (Green, col. 1, lines 17-20). Green fails to disclose or suggest a "septum seal" that is coupled to a zero seal as recited in Claim 1. Rather, for gas sealing, Green only discloses a gasket positioned in a lower cannula housing. (Green, col. 5, lines 10-12). As discussed above, Lafontaine teaches away from incorporating a gasket in the hemostasis valve described therein.

Accordingly, for at least the reasons discussed above, the applied combination of references fails to disclose or suggest all of the limitations of Claim 1, from which Claims 25 and 26 depend. Therefore, at least for the reasons that Claim 1 is distinguishable over the applied combination of references, Claims 25 and 26 are distinguishable over the applied combination of references.

### **Conclusion**

For at least the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowability is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of

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the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, John F. Heal, at (949) 713-8283 to resolve such issues promptly.

Respectfully Submitted,

APPLIED MEDICAL RESOURCES

BY



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